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Efficacy of Physiotherapy Treatment for Female Urinary Incontinence

by

Christine C. Mummery

A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfilment of the requirements for the degree of Master of Science

Department of Physical Therapy

Edmonton, Alberta

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The undersigned certify that they have read, and recommend to the Faculty o f Graduate Studies and Research for acceptance, a thesis entitled Efficacy of Physiotherapy Treatment for Female Urinary Incontinence submitted by Christine Mummery in partial fulfilment of the requirements for the degree of Master of Science

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Abstract

This study examined the effects of physiotherapy for female urinary incontinence. Eleven women (5 with mixed and 6 with stress UI), age 39-74 years, underwent 3 pre-treatment testing periods, an intervention period and a post-treatment test. The physiotherapy intervention emphasized pelvic floor muscle retraining through active exercise and, in some cases, biofeedback and neuro-muscular electrical stimulation.

Pad weight, number of episodes of incontinence and voiding frequency recorded in a bladder diary, and an incontinence-specific health-related quality of life measure were the outcome measures. Each measure was tested 4 times.

Four one-way repeated measures ANOVA and repeated comparisons revealed, that for all measures, there were no significant differences between the first 3 testing periods, and significant changes between the third pre-treatment tests and the post-treatment tests. These findings suggest that physiotherapy treatment for women with stress and mixed UI was effective in reducing severity of symptoms and impact that incontinence has on health-related quality of life.

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Table of Contents

		page
Chapter 1 - Introduction		1
Chapter 2 - Literature Review	Prevalence and Cost	2
	Impact of UI on the Individual	2
	Background on UI Etiology and Management	4
	Results of Efficacy Studies	5
	Outcome Measures	8
	Summary	12
Chapter 3 - Methods	Specific Objective	17
	Study Design	17
	Sample Size	17
	Testing	18
	Intervention	19
	Variables	21
	Statistical Analysis	21
Chapter 4 - Results	Description of Subjects and Intervention	24
	Descriptive Statistics	24
	Change over Time	25
	Effect Size	25
Chapter 5 - Discussion	Outcome Measures	32
	Generalizability of Results	34
	Compliance to Treatment	35
	Limitations to the Study	35
	Future Research	36
	Conclusion	37
References		38
Appendix A	UI-HRQL Questionnaire	45
Appendix B	Information Sheet and Consent Form	46
Appendix C	Visual Analogue Report Forms	48
Appendix D	Data Normality and Transformations	50

List of Tables

Table	Title	Page
1.1	Summary of reviewed efficacy studies	13-14
1.2	Systematic reviews of randomized controlled studies	15
3.1	Effect size estimations	23
4.1	Gynecological history of the study sample	26
4.2	Subjects' background details, outcome scores and descriptive statistics	27
4.3	Correlations between dependent variables	28
4.4	Results of the one-way repeated measures ANOVA	29
4.5	Significance between the time periods for each dependent variable	29

List of Figures

Figure	Title	Page
4.1	Mean change in pad weight over time	30
4.2	Mean change in no. of UI episodes over time	30
4.3	Mean change in HRQL score over time	30
4.4	Mean change in Voiding Frequency over time	30

List of Definitions and Abbreviations

For consistency and ease of reading, the following definitions and abbreviations will be used:

Agency for Health Care Policy and Research (AHCPR) – an American Federal agency responsible for facilitating the development, review and updating of clinically relevant guidelines to assist healthcare practitioners in the diagnosis and management of clinical conditions.

Biofeedback (BFB) – visual or auditory information about pelvic floor muscle contractions that is fed back to the patient to assist with muscle retraining.

Detrusor – the detrusor muscle is the smooth muscle in the wall of the urinary bladder that contracts the bladder and expels the urine.

Detrusor Instability – involuntary contractions of the detrusor as in urge incontinence.

Health-related Quality of Life (HRQL) – Quality of life related to health status. May be measured with generic instruments such as the SF-36 or with disease-specific instruments (see UI-HRQL).

Mixed Incontinence (mixed UI) – the combination of urge UI and stress UI symptoms.

Neuro-muscular Electrical Stimulation (NMES) – the application of electric current to nerve pathways or directly to muscle fibers, to induce a therapeutic response.

Pelvic Floor Exercises (PFE) – Repetitive active exercise of the pubococcygeus muscles to improve urethral resistance and urinary control.

Pelvic Floor Muscles (PFM) – A group of muscles that provide a floor or hammock for the abdominal organs. Levator ani and pubococcygeus are the dominant muscles in the group.

Stress Incontinence (stress UI) – incontinence characterized by the involuntary loss of urine doing physical exertion, or actions that increase intra-abdominal pressure such as coughing, laughing.

UI-HRQL – a disease-specific (urinary incontinence) health-related quality of life instrument, designed by Shumaker et al (1994) and Uebersax et al (1995).

Urge Incontinence (urge UI) – involuntary loss of urine associated with a strong, sometimes uncontrollable desire to void.

Urinary incontinence (UI) – Involuntary loss of urine sufficient to be a problem.

Chapter 1
Introduction

Urinary incontinence (UI) is defined as "the involuntary loss of urine sufficient to be a problem" (Agency for Health Care Policy and Research, 1992). It is a poorly reported and diagnosed medical problem estimated to affect 15-30% of all women over 60 years of age and between 10-25% of women under age 60. (AHCPR, 1992). This estimate does not include women in long term care facilities where it is believed that 50% of residents are incontinent. UI is associated with significant physical and psychosocial effects ranging from shame, fear of discovery, loss of self-esteem to the loss of ability to participate in physical activity, social events or employment. Several recent efficacy studies (Bo et al, 1999; Fonda et al, 1995; Holtedahl et al, 1998; Lagro-Janssen et al, 1991 and Burns et al, 1993) have demonstrated encouraging results with the conservative treatments provided by physiotherapists. Therefore, there is a growing interest in developing therapeutic programs incorporating these techniques.

Clinicians and program planners within the Women's Health field need information on the effects and applicability of physiotherapy programs for the 3 common types of urinary incontinence. Most available literature refers only to stress UI (the involuntary loss of urine during activities that increase abdominal pressure beyond what the pelvic floor structures can counteract). However, over 50 % of women with UI have mixed or urge symptoms (Diokono, 1994).

Treatment of urinary incontinence with physiotherapy has only recently become available to Albertans, since several physiotherapists have obtained specialized training, and computer-assisted biofeedback and NMES equipment has been purchased. Some funding has become available for these physiotherapy programs comes through the public health care system. However, the funds allocated are hard-pressed to meet the demands, as large numbers of women have become aware of the benefits of treatment. The results of this project will, in addition to assisting clinicians, will provide information to planners and managers in allocating resources.

Chapter 2
Literature Review

Prevalence and Costs

Urinary incontinence, according to the U.S. Department of Health and Human Services (AHCPR, 1992), affects 10-24 % of women under 64 years of age, 15-30 % of community-living women over 65 and over 50% of institutionalized elderly. Over 30% of all women over the age of 55 experience episodes of urinary incontinence at least once a week. (Diokono, 1993). It is believed that less than half of those individuals, living in the community with UI, consult with a health care provider about their problem. Others avoid seeking assistance either because of embarrassment and shame or because they believe it is a normal part of ageing (AHCPR, 1992; Burgio & Robinson, 1986).

Urinary incontinence is a costly medical and social problem. Erelund and Rundgren (1987) have identified large additional institutional costs for care of patients with UI due to the fact that urinary incontinence is an important contributing factor in the decision to institutionalize elderly people. Hu (1990) reports that 50% of all nursing home residents in the United States are incontinent of urine on a regular basis. Incontinent individuals are also estimated to have longer hospital stays by nine days per given year (Katz et al, 1982).

The costs associated with community-living individuals managing with incontinence include incontinence supplies, extra laundry, time off work to deal with leakages and medical appointments, travel costs to appointments, medical and surgical fees, hospitalizations and costs of complications such as skin irritation and urinary tract infections. Hu (1990) estimates that the total costs of incontinence for individuals living in the community in the U.S. are $7 billion per year (in 1987 dollars). This figure is derived from an estimated cost of $2.50 per day or $912.50 per year for every incontinent person. Assuming Canada has a similar prevalence for UI, the costs in this country can be estimated to be $700 million per year.

The Impact of Urinary Incontinence on the Individual

Several writers have described the negative psychosocial effects of UI. Shame, fear of discovery and embarrassment were reported by many authors (Talbot, 1994; Shumaker et al, 1994; Lagro-Janssen et al, 1992), as frequent effects of urinary incontinence. Loss of confidence and self-esteem were reported by others (Talbot, 1994; Lagro-Janssen et al, 1992). Lagro-Janssen et al (1992) found that 82% of respondents felt their UI caused a decrease in their emotional well-

being. Incontinent elderly women scored significantly higher in emotional disturbances than an age-matched sample of the total population (Grimby et al, 1993). The incontinent women also reported social isolation more frequently. Distress and anxiety were prevalent findings in several studies (Hunskaar & Vinsness, 1991; Shumaker et al, 1994; Talbot, 1994).

Women with UI make significant changes in lifestyle in order to cope with their problem. Both Lagro-Janssen et al (1992) and Shumaker et al (1994) reported that women reduced their participation in recreational pursuits, especially sports and fitness activities due to UI. They gave up or reduced social activities like dancing, meetings and parties. Several writers have shown that women are less willing to travel away from their houses (Diokono, 1994; Shumaker et al, 1994; Grimby et al, 1993). Women with incontinence reported taking extra precautions, such as taking extra clothes, changing pads frequently to avoid skin irritation and ensuring they knew the location of washrooms. Some women go to even greater lengths to cope with their incontinence. Talbot (1994) found that women coped with UI by avoiding social contacts, avoiding intimacy, and concealing behaviors. They developed elaborate schemes to stay dry, change clothes and avoid embarrassing smells (Lagro-Janssen et al, 1992; Breakwell & Noble Walker, 1988; Diokono, 1994).

No reports of lost employment opportunities are reported in the literature for this condition. Perhaps the studies do not address this because they reported on older women who are retired or were never employed outside the home. However, it seems that job seeking and job retention would be affected by this unpleasant and disruptive condition.

Because UI affects psycho-social and emotional domains and impacts on activities of daily living, we can conclude that UI adversely affects quality of life to a significant extent. (Hunskaar & Vinsness, 1991; Lagro-Janssen et al, 1992). Grimby et al (1993) found that women with UI scored significantly lower on the Nottingham Health Profile Questionnaire than age-matched women from the general population. This questionnaire has been used extensively to assess the influence of various illnesses and disabilities on quality of life. Diokono (1994) reported that older women with UI showed statistically significant differences on depression and life satisfaction scores than continent women of the same age, as measured by the Sickness Impact Profile (SIP). Life satisfaction, as measured by the SIP also declines with increasing severity of UI (Diokono, 1994).

Researchers have compared the effects of the different types of UI on quality of life. Hunskaar and Vinsness (1991) found that the impact of UI was "age and symptom-dependent".

Urge incontinence had a greater impact on health-related quality of life than stress UI for older women. Grimby et al (1993), on the other hand, found no significant differences in quality of life scores between the types of UI. Hunskaar and Vinsness (1991) found that Sickness Impact Profile scores did not correlate with duration of UI. They theorized that women do not adapt or "get used to" the impact of incontinence over time.

Background on UI Etiology and Management

There is significant evidence that pudendal or pelvic nerve disturbances result in stress incontinence (Snooks et al, 1985). The denervation of nerves results in reduced awareness of the pelvic floor area, and reduced strength and endurance of the pelvic floor muscle groups (Appel, 1998). The nerve disruption may occur due to pregnancy and birth trauma, chronic increased intra-abdominal pressure and ageing factors. Bθ et al (1988) found that 31% of incontinent women could not contract their pelvic floor muscles correctly, even after some instruction.

Urge incontinence, or detrusor instability, implies that the bladder is incapable of storing adequate volumes of urine, due to involuntary contractions of the smooth muscle of the bladder. This may be caused by neurologic injury, inflammatory processes or idiopathic causes (Appel, 1998).

Surgical treatment for stress incontinence has been undertaken for the last ninety years. The procedures aim to lift and support the urethro-vesical junction, and improve the efficacy of the detrusor. Black and Downs (1992) systematically reviewed the evidence of effectiveness of surgery for stress UI. They concluded that evidence was weak, and large, rigorous, prospective studies are urgently needed. In addition, complication rates were not reported, and therefore the relative safety of the procedures was unknown.

Even though Arnold Kegel popularized conservative treatment for the alleviation of incontinence problems in the 1940s, little medical attention was paid to conservative measures until recently. The AHCPR Clinical Practice Guidelines (1992) concluded that non-surgical therapy should be considered as the first line of therapy for UI because the benefits are comparable to surgery, there are no side effects or complications and these treatments are less costly than surgery. The AHCPR panel recognized the need to evaluate these interventions further due to inadequacies in previous research. The available research problems included poorly reported and categorized UI, major variations in treatment protocols, inconsistent outcome measurement and poor long-term follow up of subjects.

Physical therapy, which emphasizes pelvic floor muscle retraining, with or without other treatment adjuncts such as biofeedback, neuro-muscular electrical stimulation (NMES), is the mainstay of conservative treatment. The theoretical basis for pelvic floor muscle re-education as a treatment for stress incontinence is as follows: recruitment of and strengthening of pelvic floor muscles improves the support of the pelvic organs against gravity and against increased intra-abdominal pressures, and improves the efficiency of the sphincteric action around the urethra. It is also thought that a strong pelvic floor contraction "clamps off" the rising pressure in the urethra as it is pressed against the pubic symhysis (Berghmans et al, 1998). It is postulated that a well-timed, strong PFM contraction may prevent urethral descent and urine loss during abrupt intra-abdominal pressure rise (as during coughing). Muscle exercise, causing muscles to hypertrophy, increases the mechanical pressure on the urethra (Bø, 1997).

In urge incontinence, the aim of physical therapy is to inhibit the detrusor (the smooth muscle of the bladder) contraction by using a negative feedback loop, wherein detrusor activity is inhibited by pelvic floor muscle and sphincteric contraction. Stimulation of afferent sacral nerves within the pelvis increases the inhibitory stimuli, hence reducing bladder contractility (Fall et al, 1986).

The various adjunct therapy modalities, such as biofeedback and vaginal cones, are simply techniques to facilitate recruitment and muscle strengthening of the pelvic floor musculature. Neuro-muscular electrical stimulation (NMES) is aimed at mirroring voluntary muscle contractions to increase strength and endurance of the muscle group. In urge incontinence, the aim of NMES is to inhibit detrusor contraction, through the negative feedback loop previously described.

The use of electrical stimulation in restoring muscle function is disputed. Many researchers have concluded that voluntary contractions are more effective than electrical stimulation (Bø, 1998). Bo and Talseth (1997) demonstrated that voluntary contraction is more effective in increasing urethral pressures than electrical stimulation. They suggest that NMES should be restricted to women not aware of how to contract the pelvic floor muscles, and after learning to contract, they should continue with intensive voluntary contraction exercises.

Results of Efficacy Studies

The efficacy studies published since 1990 are summarized in Table 1.1 at the end of this chapter. The majority of trials studied the effects of conservative treatment on genuine stress UI,

with smaller numbers addressing all types of UI (stress, urge and mixed). The following review of literature divides the research into 4 groups:

1. Effects of pelvic floor exercises (PFE) alone
2. Effects of biofeedback compared to PFE
3. Effects of NMES compared to sham/placebo or compared to PFE alone
4. Effects of combined therapy or conservative management.

Pelvic Floor Exercise Alone

Five studies compared PFE to a control or deferred treatment situation. Four studies specifically reported on stress UI, while Fonda et al (1995) did not specify the type of UI. Three of the four studies looking at stress UI found that significant improvement was obtained both in pad testing and in subjective measures (Bø et al, 1990; Dougherty et al, 1993; Lagro-Janssen et al, 1991). The fourth study (Ramsay et al, 1990) found no change in pad testing nor subjective results. This study experienced a 50% drop out rate and poor adherence to treatment by the therapy group. Fonda et al (1995) found that 87% of patients treated with PFE and advice, were either improved or cured, while a "deferred treatment" group did not improve during the wait period.

Pelvic Floor Exercises vs. Biofeedback

Studies that examined the effects of PFE alone compared to BFB, have not shown major differences in improvement. Burns et al (1993) and Berghman et al (1996) found no differences in the improvement levels between PFE and BFB groups (with stress UI), although Berghman et al (1996) found that the BFB group reached the maximum improvement effect in half the time of the PFE alone group.

NMES vs. placebo NMES or vs. PFE

Sand et al (1995), using 52 stress UI subjects, compared active NMES to sham stimulation and found that the NMES group achieved significant improvement in all measures, whereas the placebo group made no improvement. Blowman et al (1991), with a much smaller sample size (n=13) found that 6 out of 7 subjects in the treatment group achieved dryness, however, 2 out of 6 in the placebo group also improved significantly.

Smith (1996) compared NMES to PFE in 18 stress UI subjects. There were no significant differences between groups for leakage episodes (50-66 %) improvement rate in both groups). Hahn et al (1991) found no significant difference between an NMES treatment group and a PFE

group, with both groups improving to some extent. Caputo et al (1993) and Bent et al (1993) demonstrated improvement for all 3 types of UI using NMES therapy. However, their one-group design did not allow for any comparisons with other forms of treatment or with a control.

Smith (1996) also compared NMES treatment of urge UI with anti-cholinergic medication. There were a total of 38 subjects and the outcome measure was a subjective rating of cure/improved/no change. In the NMES group, 22% were "cured" and 50% were improved, whereas in the Medication group, 15% were cured and 35% were improved. However, these results were not statistically significant.

Combination Therapy

Several studies have examined the effects of a combined therapy program on mixed types of UI. Holtedahl et al (1998), randomly allocated 90 subjects to a control group or to a treatment group that received advice, Estriol medication (vaginal cream), PFE and home NMES. The severity of UI dropped significantly in the treatment group, while the control group reported no change. Frequency of UI episodes reduced in both groups. Davila and Bernier (1995) used a combined therapy treatment for subjects with all 3 types of UI. They reported 88-89% reduction in number of UI episodes in all types of UI.

Two authors have done systematic reviews of all randomized controlled trials (Table 1.2). Berghman et al (1998) looked at 24 published articles on stress UI and conservative treatment. Their review suggests that PFE alone may be an effective treatment for female stress UI. Cure and satisfaction rates for PFE treatment may be as high as 60-70%. Studies comparing biofeedback to PFE alone showed little difference. They hypothesized that if BFB is useful, it may be only with patients with insufficient awareness of pelvic floor contraction. Therefore studies that diagnose and differentiate those specific subjects need to be performed. The studies that reviewed NMES suggest that active stimulation is more effective than sham stimulation. However, NMES may be no more effective than PFE alone. They suggest that NMES may be appropriate for those subjects who are initially unable to contract the pelvic floor muscles.

Bø (1998) did a systematic review of all available studies on NMES in the treatment of UI. Ten studies that were of sufficient rigour and sample size were evaluated. Bø (1998) agreed with Berghman's conclusion in that NMES does not seem to be more effective than PFE. As noted in the previous study (Bo et al, 1988), NMES may be effective in the initial stages of therapy for the 30% of incontinent women who cannot contract the pelvic floor muscles correctly. Bø

indicated there was a need for further controlled studies, especially to examine the effects of conservative therapy for urge UI.

Compliance and drop out rates

Because physiotherapy for UI requires patients to attend appointments, perform home exercises and change behavior, compliance and drop out rates are important aspects of an evaluation of effectiveness. Success of treatment can be reported as artificially high if many of the initial subjects drop out, since it is likely that the subjects experiencing improvement will complete the treatment and those not improving may not adhere or drop out. Drop out rates reported in the studies in Table 1.1 range from 0% (Berghman et al, 1996) to 50% (Ramsay et al, 1990). Fonda et al (1995) were the only investigators who tested for differences in demographics and pre-treatment measures between subjects that completed the treatment and those who dropped-out. Fourteen out of 73 (19%) subjects dropped out of their study, and no demographic differences were found between subjects who completed the treatment and those who dropped out. This would suggest that drop-outs do not positively bias results.

Length of Treatment and Follow up Phases

The treatment phases of the studies ranged from 4 weeks (Burgio et al, 1986; Blowman et al 1991; Berghman et al, 1996) to 6 months (Bo et al, 1990; Holtedahl et al, 1998). Most studies however, were 6-12 weeks in duration. Ten of 16 studies in Table 1.1 reported a follow up period ranging in length from 6-12 months. Most studies that reported an original improvement in UI status also reported that improvement was well maintained during the follow up period (Holtedahl et al, 1998; Burns et al, 1993; Caputo et al, 1993; Fonda et al, 1995). One study reported a relapse of 10% in the follow up period (Dougherty et al, 1993).

Outcome Measures

Evaluation of treatments for UI requires reliable and valid measures that are inexpensive, sensitive to change and not overly invasive. Researchers have developed objective measures of severity of incontinence, such as collecting the loss of urine with a perineal pad, which is then weighed (Lose et al, 1988; Griffiths et al, 1990; Moore et al, 1993). Self-reported incidences of leakage and self-reported frequency of voiding are other means of quantifying improvement. These measures are frequently used by clinicians as assessment and re-assessment measures. PFM strength measures (or contractional force measures) are sometimes used to document improvement, however the test-retest reliability for pressure-sensitive instruments has been shown to be poor

(Knight and Laycock, 1992). Researchers have also commonly used subjective ratings of improvement, however there has been little evidence that the questions used to test these subjective ratings are valid.

Researchers have recently recognized the need to use more than objective impairment outcome measures in physiotherapy research (Johnston et al, 1992). Although some studies have used patients' perception of improvement as outcome measures of UI treatment, few studies have used a handicap or quality of life measure. General health-related quality of life scales and instruments have been used by researchers, not to measure treatment efficacy, but to understand the psychosocial impact of UI on sufferers. However Shumaker et al (1994), and Uebersax et al (1995) have developed a standardized, validated inventory of symptoms and the impact on quality of life. This disability/handicap level detects change in functional status and quality of life.

Four outcome measures have been selected for use in this project in order to address Lohr's (1988) and Benjamin's (1995) call for effectiveness research that uses patients' perception of improvement, as well as the World Health Organization's imperative to measure impairment, disability and handicap levels of outcome measures (WHO, 1980). These measures are: the Health-Related Quality of Life Instrument for women with urinary incontinence, the 24-hour pad test, episodes of incontinence and voiding frequency. These measures are discussed in more detail below:

UI Health-related quality of life Instrument

The Urinary Incontinence Health-related Quality of Life (UI-HRQL) instrument was developed specifically for women with urinary incontinence. It measures their perception of the severity of the problem, their distress about the problem and its impact on their functions, roles and emotional status (Shumaker et al, 1994). It was originally a 50-item instrument with internal consistency (Cronbach's alpha coefficients) of 0.77-0.89 (Shumaker et al, 1994). Test-retest reliability over a one week span was 0.71.

The investigators also tested for construct validity by examining correlations between the UI-HRQL and generic health status instruments and impairment measures of UI. The UI-HRQL subscales correlated (between $r=0.37$ to $r=0.52$) with the Sickness Impact Profile, the RAND 36-Item Health Survey and the C.E.S. Depression Scale. The UI-HRQL subscales correlated significantly with number of episodes of incontinence and pad weight (between $r=0.27$ and $r=0.34$). Interestingly, correlations between generic health status measures and pad weight and episodes were very low (-0.05- 0.11). The authors suggest that because the UI-HRQL correlates only

moderately with generic health-related instruments, but relates highly with UI impairment measures, it captures something beyond what generic HRQL measures capture, providing support for the use of a disease-specific quality of life measure.

The UI-HRQL instrument has also been shown to detect change after a 12-week treatment session. The HRQL total score showed a mean change of 61.5 points, while the mean changes for number of incontinent episodes and pad test were 4.3 and 10.6 respectively. The differences in UI-HRQL score over time correlated $r=0.51$ ($p<0.01$) with the number of incontinence episodes and $r=0.23$ ($p<.01$) with the pad test (Shumaker et al, 1994).

Uebersax et al (1995) used multiple regression analyses to shorten the 50-item version of the HRQL instrument down to 16 items. The short version still has two parts: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. The former has 9 questions on how urine leakage affects: household chores, physical recreation, entertainment activities, travel away from home, participation in social activities, and emotional health (nervousness, depression, frustration). The Distress portion of the tool has 7 items inquiring about urination frequency, leakage related to a feeling of urgency, leakage related to activity, coughing or laughing, small amounts of leakage, difficulty emptying bladder and pain or discomfort in lower abdomen or genital area.

The validity of the short form was tested by correlating the short form results with the scores from the long form for 162 women with UI. The 7-item impact questions correlated $r=0.97$ ($p<0.001$) with the long form. The 6-item distress questions correlated $r=0.93$ ($p<0.001$) with the long form. The 13 questions are responded to with "not at all, slightly, moderately or greatly" (scoring 0 - 3) for a maximum score of 39 (a high score indicates more severe UI and a greater impact on quality of life). The short form minimizes respondent burden, while still measuring the distress and impact of UI. Please see Appendix C for the complete questionnaire.

Pad Testing

Severity of UI can be quantified by measuring the amount of urine leakage as an impairment measure. Perineal pad weighing provides a noninvasive, accurate, simple and inexpensive method of objectively measuring urine loss. Weight loss due to evaporation was demonstrated to be negligible after 7 days and only 5% weight loss after 8 weeks (Versi et al, 1996). Pad weight gain in normal subjects was measured by 2 separate researchers (Versi et al, 1996 and Siltberg et al 1997) in order to take into account the possibility of weight gain not due to urine (vaginal discharge, perspiration, etc.) Both researchers agreed that normal, asymptomatic

female subjects produced a mean weight gain of 4.0 grams / 24-hour period, with a 99% upper confidence limit of 8 g/24h. Therefore pad weight gain of greater than 8 grams can be regarded as positive for incontinence. Versi (1996) also found that pad testing was favorably accepted with 83% of subjects (161) completing the test perfectly.

Two categories of pad testing have been used in previous literature: those carried out in the laboratory or hospital over a short time and those conducted by subjects in their home and work environment over a longer timeframe. The International Continence Society (Lose et al, 1988) recommended the use of the one-hour Pad Test specifically for measuring change in stress UI in a lab or hospital-setting. The one-hour test includes a physical activity component, which attempts to capture leakage during activities that increase abdominal pressure. The one-hour test has been criticized as being artificial, and limited only to a screening test because of its poor sensitivity (Versi et al, 1988). The reproducibility of the one-hour test is improved by catheterizing the subject to inject a standardized volume (Lose et al 1988) into the bladder prior to starting the test, however, this detracts from the noninvasive nature of the test.

Griffiths et al (1990) suggested that a 24-hour home pad test was more reproducible than the 1-hour test. The 24-hour test had a test-retest correlation of 0.75 whereas the one-hour pad test had a correlation of 0.58. They also demonstrated that the 24-hour test could detect change in UI symptoms after 4 weeks of intervention. Post-intervention pad weights were reduced by 62%.

Versi (1996) compared the reproducibility of the 24-hour test with the 48-hour home test. Two 24-hour pad tests done with the same subjects, one week apart, produced test-retest correlation coefficients and 95% confidence intervals of 0.90 (0.87-0.94). The 48-hour test correlation coefficients for tests held one week apart were slightly better than the 24-hour test at 0.94 (0.93-0.95). Versi also examined the pad test's ability to detect incontinence as compared to the more invasive video urodynamic study. They found high concordance between the pad test result and video urodynamics (Kappa 0.653). However, the pad test seemed to produce a 28% false positive. That is 12 of the 57 women who had positive pad tests were negative during video urodynamics testing. However, 8 out of the 12 women who had positive pad tests and no abnormality on urodynamic testing went on to show abnormal cystometry tests. This suggests, in accordance with Griffiths et al (1990), that home pad testing may effectively detect functional urine loss better than urodynamics

Bladder Diary Measures

Frequency of urinary incontinence, or **number of episodes of incontinence and voiding frequency** are common objective measures of UI severity. Episodes of UI reflect the inability of the anatomical structures of the pelvic floor to perform normally, therefore it can be considered an impairment measure of UI. Voiding frequency, used predominantly to measure severity of urge incontinence, is also an impairment measure as it reflects the inability of the detrusor to relax and allow bladder filling (AHCPR, 1992). Self-monitoring using a daily diary is a useful method of obtaining voiding behavior data in the individual's own environment, under actual living conditions. The AHCPR Clinical Practice Guidelines (1992) recommend that UI sufferers keep a written record, as part of a UI evaluation, to determine underlying causes and judge treatment efficacy. Wyman et al (1988) investigated the test-retest reliability of a one-week bladder diary with incontinent women (n=50) and found that episodes of incontinence (r=0.89-0.92) and voiding frequency (r=0.85-0.92) were highly reproducible.

Summary of Review of Literature

Urinary incontinence is a common problem amongst middle-aged and older women and is costly in terms of health care expenses, and personal grief and inconvenience. Several researchers have demonstrated that conservative treatment, specifically PFE and other modalities, can be helpful in reducing the severity or curing the problem. The outcome measures commonly used to assess benefit of treatment are urine loss weighed in pads, self-reported episodes of incontinence and voiding frequency, subjective measures of improvement. This study will look at the benefits of an actual physiotherapy program provided in a clinic setting. It will examine the changes in UI severity over time, by measuring pad weight and episodes of UI. Health-related Quality of Life will be measured, as well, in order to examine the change in the impact of UI severity on psycho-social and functional issues.

Table 1.1
Summary of reviewed efficacy studies

Author, Year	Type of Treatment	Type of UI	Study Design / N	Outcome Measures	Withdrawal Rate	Treatment time/ Follow up (FU)	Results
Bø et al, 1990	PFE	Stress	Treatment vs. control / N=52	Pad test Subj.	"few"	6 months / no FU	Treatment group:↑ in urine loss Control group: no change
Ramsay et al, 1990	PFE	Stress	Treatment vs. control, random N=44	Pad test Subj. Perinometer	> 50%	3 months / no FU	No change in either group, poor adherence
Lagro-Janssen et al, 1991	PFE	Stress	Treatment vs. control, random N=66	Subj. Diary	13%	3 months / no FU	85% in PFE group reported improvement or cure # of episodes ↓ in PFE group ($p<.01$)
Dougherty et al, 1993	PFE	Stress	One group, pre-post N=80	Pad test Diary Subj.	13/80=16%	16 weeks / 1-2 yrs. FU	↓ urine loss and episodes relapse of 10% in 2 year FU
Fonda et al, 1995	PFE	Not specified	Treatment vs. control N= 73	Subj. Diary	14/73=19%	Not specified / 1 year FU	25%-62% reported being "cured" or "improved", no change in control, maintained in FU
Burgio et al, 1986	PFE vs. BFB	Stress	2 groups, N=24	Pad test, Diary, Sphinct.press.	*	4 weeks / 6 mon. FU	BFB group had ↑ sphincter pressures, episodes compared to PFE group
Burns et al, 1993	BFB vs. PFE	Stress	3 groups,:BFB, PFE, control N=135	Diary EMG readings	17/135=13%	8 weeks / 22 week FU	↓ in episodes for both PFE and BFB groups, no change in control group, sustained in FU
Berghman et al, 1996	BFB vs. PFE	Stress	2 groups, random N=40	Pad test Diary	0	4 weeks / no FU	No differences in groups, but effect reached in half the time by the BFB group
Blowman et al, 1991	NMES	Stress	2 groups, NMES vs. placebo, random N=14	Diary Perinometer	1/14	4 weeks / 6 mon. FU	6/7 in NMES group achieved dryness 2/7 in placebo group improved

Author, Year	Type of Treatment	Type of UI	Study Design / N	Outcome Measures	Withdrawal Rate	Treatment time/ Follow up (FU)	Results
Hahn et al, 1991	NMES vs. PFE	Stress	2 groups N=20	Pad test Subj.	*	5 mon. / 4 year FU	No group differences
Sand et al, 1995	NMES	Stress	2 groups, NMES vs. placebo, random N=52	Pad test Diary	8/52 = 15%	12 weeks / no FU	Improvement in all measures for the treatment group, no changes in control
Bø et al, 1999	NMES vs. PFE	Stress	3 groups, NMES, PFE and control, random N=119	Pad test Diary Subj.	12/119=10%	6 months / no FU	↓ episodes in PFE group only, ↓ subj. ratings in both PFE and NMES groups Compliance better in PFE group
Caputo et al, 1993	NMES	Stress, urge, mixed	Pre-post test N=76	Pad test Diary	*	6 weeks / 6 mon. FU	Stress improved 79-89% Urge improved 63-73% Mixed improved 67-70%
Bent et al, 1993	NMES	Stress, urge, mixed	Pre-post tests N=45	Pad test Diary Subj.	*	6 weeks / no FU	40% improvement in all types
Smith, 1996	NMES vs. PFE	Stress	2 groups, random N=18	Diary Subj. Urodynamics	0%	4-6 weeks / no FU	No difference improvements between NMES and PFE groups
Smith, 1996	NMES	Urge	2 groups – NMES vs. anti-cholinergic drugs (control)	Diary Subj. Urodynamics	1/38=3%	4-6 weeks / no FU	50% ↓ in episodes for control group and 72% ↓ in episodes for NMES group, but not significant.
Davila & Bernier, 1995	Combined	Not specified	Pre-post tests N=104	Diary Subj.	*	12 weeks / no FU	89-92 % ↓ in episodes
Holtedahl et al, 1998	Combined	Not specified	2 groups, treatment vs. control, random N=90	Diary Subj.	6/90 = 5%	4-6 mon. / 12 mon. FU	↓ in episodes and rating of severity for treatment group only, Improvement maintained in FU

* refers to not reported FU refers to follow up random – refers to random allocation subj. – refers to subjective rating of severity

Table 1.2
Systematic Reviews of Randomized Controlled Studies of Conservative UI Treatment

Author, Date	Type of UI	F. Treatment Types Reviewed	Number of Studies Reviewed	Results / Recommendations
Berghmans et al, 1998	Stress	PFE with or without other modalities	24 studies reviewed; 11 found to be of sufficient quality	• Strong evidence that PFE is better than no treatment • Strong evidence that BFB is no more effective than PFE • Active NMES is more effective than sham NMES, but no more effective than PFE alone.
Bø K, 1998	Stress Urge	NMES	10 studies reviewed (9 for stress and 1 for urge)	Stress: No evidence of differences between NMES and PFE alone Urge: Little evidence to confirm that NMES is more effective than drugs (small sample sizes) Need well-designed controlled studies to look at urge.

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16

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UMI

Chapter 3

Methods

Specific Objective

The objective of the study was to determine whether the physiotherapy treatment provided at the Royal Alexandra Hospital Women's Clinic is effective in reducing the severity of UI.

Study Design

The study used a repeated measures design. Clients who were on a waiting list for physiotherapy for their incontinence were recruited and tested 3 times prior to commencement of treatment. Measurements taken at 6, 3 and 0 weeks prior to treatment were used as control measures. The final measurements were taken at the end of the treatment period. The study sample was one of convenience. Women who presented with a diagnosis of UI to the Royal Alexandra Hospital's Uro-therapy Program, were eligible. Ethics approval was obtained from the Capital Health Authority Ethics Committee prior to initiation of the project.

Women were referred to the Clinic by a specialist in uro-gynecology, by other urologists or by family physicians. Clients could also self refer. The research coordinator approached all potential subjects, performed a screening assessment to ensure they met the inclusion criteria, explained the research project and obtained informed consent (Appendix A).

Women were excluded from the study if they:

- had urinary incontinence caused or complicated by cognitive or mobility deficits;
- were proceeding with other forms of treatment for UI such as surgery or medication;
- were pregnant;
- had a pacemaker (as the electro-therapy component of the treatment is contraindicated when a pacemaker is in situ);
- had UI caused by a neurological dysfunction, e.g. multiple sclerosis or stroke;
- were unable to understand English well enough to give informed consent;
- had started or stopped using hormone-replacement therapy within 90 days of the beginning of the study.

Sample size

The sample size required was calculated to ensure that a power of 0.80 and an alpha of 0.01 were achieved. Alpha of 0.01 was required to allow for the multiple dependent variables, i.e. 4 outcome measures (Cohen 1988). To estimate effect size, results of previously referenced studies were used. Effect size was considered to be the difference between the pre-test and post-test means

divided by the standard deviation of the initial mean. Effect sizes in the literature ranged form 0.96 to 3.0 for all 4 measures. Table 3.1 at the end of Chapter 3 summarises the results of previous studies used to estimate sample size.

Cohen (1992) defines anything over 0.80 as a "large" effect size, and requires 18 subjects for a repeated measures analysis. However, Kraemer and Thieman (1987) suggest a sample of 10 for repeated measured to achieve a power of 0.80 with an effect size in excess of 1.0 at an alpha of 0.01. Recruitment of eighteen subjects was the initial goal of the study, however due to various changes in program funding and referral sources, only 11 subjects were recruited during the study period.

Testing

The following demographic data were collected on all participants when they agreed to participate in the study:

- age
- years since onset of symptoms
- presence of co-morbidities
- past history of obstetrical/gynecological surgeries
- childbearing history (parity)
- current medications
- menopausal status

The 4 outcome measures, described in the literature review were administered in the same fashion at 6, 3 and 0 weeks prior to the treatment commencing.

The **UI-HRQL Instrument**-short form (Uebersax et al, 1995) is used in this study as a disability / handicap level measure (WHO, 1980). It is a 13-item paper form (see Appendix B), with a possible range of scores for each item of 0 – 3. Low scores indicate low severity and little impact on quality of life and high scores indicate the reverse. The maximum score is 39.

The **48-hour home pad test** was utilized for this study as the objective impairment measure. All dry weights of the test pads were recorded. Participants were instructed to use only the pre-weighed pads during the test period, starting from the first pad as soon as they got up in the morning and continuing for a full 48-hour period. They used the pads as needed, and sealed each wet pad in a plastic resealable bag. The sealed pads were returned to the clinic within 3 days of the end of the test. The data collector, who was blinded to the phase of the study the subject was in,

weighed the returned wet pads. The outcome measure was the weight of the wet pads (in grams) minus the weight of the pads prior to the test. The scale used to weigh the pads is sensitive to 0.1 gram and was calibrated before each weighing.

This study used the self-reported bladder diary strategy to obtain a total **number of incontinent episodes** and a total **voiding frequency** count. The diaries were kept for four days during the 3 pre- and 1 post-test phases. The outcome measure was the total number of episodes of UI and the total number of urinary voids over the four-day span.

At the completion of the fourth testing period, participants were asked whether they had initiated any other treatments for their UI problem during the study. Particularly they were asked about any changes in medications during this time.

Intervention

Participants were provided with a treatment program based on their individual needs, as assessed by a physical therapist. Three physiotherapists performed all assessments and treatments involved in the study. All therapists had, at the time of the study, over 15 years of clinical experience, with at least 4 years of experience in the treatment of UI. The three therapists worked exclusively in a Women's Continence Clinic. They each had attended at least one major Continence Management Course, and had demonstrated practical competencies in practical uro-gynecological assessment.

The assessment performed at the beginning of the intervention phase of the study consisted of the following:

- a complete medical and social history, specifically inquiring into the nature of the UI problem;
- a physical examination of the pelvic floor area;
- comprehensive assessment of the subjects' knowledge of the anatomy and physiology of the uro-genital system;
- inquiry into the subjects' dietary habits, bladder and bowel habits;
- assessing the subjects' ability to perform voluntary pelvic floor muscle contractions in various functional positions.

Following the assessment, treating therapists determined which type of UI each subject suffered from, using the following criteria (AHCPR, U.S. Department of Health and Human Services (1996):

Stress UI – involuntary loss of urine during any activity that increases the abdominal pressure (i.e. coughing, sneezing, lifting, exercising)

Urge UI – involuntary loss of urine associated with an abrupt and strong desire to void.

Mixed UI – combined urge and stress symptoms.

A therapy program was then designed for each subject based on the assessment findings. Pelvic floor muscle retraining was coached through manual facilitation techniques, through pressure biofeedback and through NMES. NMES was used for 2 different situations; firstly, if the subject could not perform a correct PFM contraction, or secondly for urge symptoms (negative feedback loop). If NMES was used, the following parameters were set:

Frequency: 10-20 Hz. for mixed UI and 50 Hz. for stress UI.

On-off time: 4 seconds on and 8 seconds off.

Treatment session lasted 15-20 minutes, followed by active voluntary contractions repetitions.

Subjects were given a home exercise to perform daily. It consisted of a specified number of sets of 10 repetitions of PFM contractions, held for at least 10 seconds each. At each appointment, therapists monitored whether patients were performing their PFE correctly. Therapists also provided significant positive reinforcement and coaching, as adherence to the treatment regime is very important.

Patient education was an important component in this therapy program. Subjects were taught, in lay terminology, about anatomy and physiology of the uro-genital system, about optimal diet and drinking practices, bladder training, and functional strategies for managing UI.

Subjects were discharged from treatment at the discretion of the treating therapist according to the following criteria:

1. achieve complete dryness (that is, no episodes of UI over 2 weeks of normal activity, combined with an average voiding frequency of 6-7 per day); **OR**

2. reach a plateau, where no improvement in episodes or voiding frequency has occurred in 3-4 weeks; **AND**
3. able to demonstrate independent active pelvic floor muscle contractions, so that a home program can be carried on after discharge.

At the completion of the treatment phase, each subject was asked to estimate her level of compliance to the entire treatment program by making a mark on a 10 cm. long visual analogue scale (1 being the worst possible compliance and 10 being the best possible compliance). Compliance to the therapy program consisted of attending all appointments, recording accurately in the bladder diary, following the recommended diet and bladder changes and performing the home exercise program as prescribed by the therapist. The treating physiotherapist was also asked to rate the subject's compliance, based on the criteria above, using a similar visual analogue scale. The visual analogue scales were measured and recorded by the research coordinator.

Variables

The independent variable was physical therapy treatment. The dependent variables were:

- UI-HRQL (short form)
- Objective weighed amount of urine-leakage collected with a pad over 48 hours (wet weight - dry weight in grams)
- Total number of episodes of leakage counted in a self-reported bladder diary over 4 days
- Total number of voids counted in a self-reported bladder diary over 4 days.

Statistical Analysis

Descriptive statistics and inferential statistics were obtained using SPSS 8.0. The data were tested for approximation to a normal distribution using visual inspection of histograms and using the Kolmogarov-Smirnov Statistic. Pad weight data, at all 4 times, was not normally distributed; therefore a log 10 transformation was subsequently done to all pad weight data..

The relationships between the 4 dependent measures were tested using Pearson's Product-moment Correlation in order examine how the 4 different measures performed over time.

To determine whether significant differences between measures existed over time, a one-way repeated measures analysis of variance (ANOVA) was performed for each of the 4 dependent variables: health-related quality of life, pad weight, episodes of UI and voiding frequency. The probability of 0.01 was used to test for significance, since more than one dependent variable was used.

Effect sizes were also calculated so that the magnitude of improvement could be compared with other similar studies.

Table 3.1 Effect Size Estimations

Measure	Reference	Pre-test Mean	Pre-test SD	Post-test Mean	Effect Size
UI HRQL Instrument	Shumaker et al (1994)	94.0	52.2	32.2	1.18
Pad Test	Bo et al (1990)	29	20	7	1.1
Pad Test (Grams)	Sand et al(1995)	45.2	10.2	15.4	3.0
Episodes of Incontinence	Davila and Bernier (1995)	22	6.2	2	2.85
Episodes of Incontinence	Burgio et al (1986)	6.9	4.6	1.8	1.1
Voiding Frequency	Holtedahl et al (1998)	8.5	2.1	6.5	0.96

Chapter 4
Results

Description of Subjects and Intervention

Eleven women were recruited for the study and all 11 completed the required 3 pre-intervention tests, the treatment itself, and 1 post-treatment testing period. The mean age of subjects was 56.3 years and ranged from 39-74 years. Six subjects were assessed as having stress UI and the remaining 5 were assessed as mixed UI.

The subjects reported having incontinence symptoms for a mean 9.8 years (range 1-30 years). Table 4.1 at the end of Chapter 4 presents the height, weight and gynecological histories of the subjects. No subjects reported starting or changing any other new medication or other treatments for UI during the study.

The subjects attended a mean of 10.8 treatment appointments (range 7-23), over an intervention period mean of 11.6 weeks (range 4-25). During the treatment appointments, patients were taught to perform pelvic floor muscle contractions using manual facilitation and biofeedback. Neuro-muscular electrical stimulation was used for 8 of the 11 subjects, for a mean of 8.5 sessions each, or 73% of appointments. Treatment programs started with clinic appointments three times per week and reduced to weekly as soon as consistent voluntary PFM contractions were achieved. Subjects were given daily home exercise programs as soon as correct voluntary PFM contractions were apparent. Subjects' rating of compliance to the prescribed therapy program was mean 7.82 (SD=1.3) out of 10, and therapists' ratings of their patients' compliance to therapy was very similar (7.91 [SD=.89] out of 10).

Table 4.2 presents the raw scores and descriptive statistics for the 4 dependent variables.

Descriptive Statistics

Data were checked for normality through visual inspection of histograms and with the Kolmogrov-Smirnov (K-S) test of normality. Pad weight data produced an extremely abnormal curve due to one outlier (subject #3). Because this subject was not an outlier for the other 3 dependent variables, and because of the small available sample size, a data transformation was performed according to Tabachnik and Fidell (1996) guidelines, in order to avoid excluding this subject's data in the inferential analysis. A Log 10 transformation brought pad weight data closer to normality, however the K-S statistic was still insignificant for 3 of the 4 test periods. See Appendix D for K-S scores and the resultant transformed Pad Weight data.

For all dependent variables, the largest change in mean occurred between testing times 3 and 4. Figures 4.1, 4.2, 4.3, 4.4 on the next page demonstrate the changes in means and standard deviations over the four testing periods.

The relationships between the dependent variables, as reflected by Pearson's Product-moment correlations are presented in Table 4. 3. Episodes of incontinence correlated moderately with pad weight (Pearson's r = 0.70-0.79). The HRQL scores correlated somewhat with pad weight (Pearson's r ranged from 0.48-0.74) and episodes of incontinence (Pearson's r = 0.31-0.50). Voiding frequency did not correlate with the other 3 measures.

Changes After Treatment

One-way repeated measures ANOVA's revealed significant within-subject differences for all 4 dependent variables. Table 4.4 displays the F scores for each dependent variable. Pad weight data used in the ANOVA and repeated contrasts underwent logarithm10 transformation prior to the analysis.

Repeated contrasts compared the test scores for each testing period. The contrasts demonstrated that, for each of the 4 measures, no significant difference occurred between times 1 and 2, or between times 2 and 3. However, significant differences ($p < 0.01$) did exist for all dependent variable between times 3 and 4. Table 4.5 displays the F scores for each of the contrasts.

Effect Sizes

Effect sizes were calculated for each dependent variable. Means and standard deviations from the three pre-treatment tests and means from the post-treatment test were used in the calculations. For pad weight, one outlier caused a large standard deviation in pre-test data (128), which then resulted in an effect size of 0.55. With the outlier 's data removed, the effect size for pad weight was 0.96. The other three measures were not effected by large variances. The effect size for HRQL was 1.14, for episodes of UI were 0.89 and for void frequency was 1.0.

Table 4.1

Gynecological history of the study sample

		n
Menopausal status	Pre-	3
	Mid-	3
	Post-	5
Vaginal deliveries	0	0
	1	1
	2	8
	3	2
C-sections	0	10
	1	1
Episiotomies	0	0
	1	5
	2	5
	3	1
Hormone Therapy	Yes	6
	No	5

Table 4.2
Subjects' background information, outcome scores and descriptive statistics.

		1	2	3	4	5	6	7	8	9	10	11	Mean	SD
Type of UI		stress	mixed	stress	mixed	stress	stress	mixed	mixed	stress	mixed	stress		
Age (years)		64	39	74	61	54	55	52	56	44	53	67	56.3	7.6
UI history (years)		30	6	15	3	8	3	1	10	14	5	13	9.8	8.2
Presence of Prolapse		C, R	No	No	No	C	No	No	C	U	C	No		
Weight (kilograms)		67.5	67.0	63.0	66.0	59.0	64.0	65.0	63.0	65.0	64.0	62.0	64.1	
Height (centimetres)		147	182	125	135	120	170	140	150	146	132	147	144.9	
Pad Weight	Time 1	10.9	13.6	435.3	19.3	19.9	30.3	15.2	14.7	96.5	9.7	21.5	62.4	126.0
(grams in 48 hours)	2	10.8	10.7	387.4	26.1	26.3	23.8	16.8	17.4	94.1	7.5	44.5	60.5	111.1
	3	11.0	13.0	528.0	27.6	30.8	27.2	14.5	21.0	105.4	25.8	46.3	77.3	151.8
	4	3.2	1.3	83.0	1.8	3.8	3.2	1.4	4.7	10.0	3.7	5.0	11.0	24.0
HRQL score	Time 1	10	36	36	11	9	23	8	22	29	7	16	18.8	11.1
(maximum=39)	2	14	26	34	9	8	35	7	21	26	12	20	19.3	10.1
	3	13	29	29	6	6	14	8	22	34	8	16	16.8	10.2
	4	12	7	19	3	5	9	0	10	3	2	4	6.7	5.5
Episodes of UI	Time 1	2	7	31	1	19	7	7	1	23	6	7	10.1	9.8
(in 4 days)	2	0	10	28	5	17	4	8	1	15	8	15	10.1	8.2
	3	2	18	25	6	16	5	7	0	13	7	8	9.7	7.5
	4	1	5	10	0	3	0	0	0	6	2	2	2.6	3.2
Voiding Frequency	Time 1	32	34	26	29	61	35	26	38	39	38	51	37.2	10.6
(in 4 days)	2	37	39	30	31	48	32	30	39	31	37	56	37.3	8.3
	3	28	36	23	27	44	30	28	33	39	37	48	33.9	7.7
	4	23	34	28	31	34	21	15	24	26	30	35	27.4	6.3

Prolapse types: C=cysto, R=rectal, U=uterine

Table 4.3
Correlations between Dependent Variables (* indicates $p < 0.05$)

	Pad Tests				HRQL Scores				Episodes				Void Frequency			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Pad 1	–	.99 *	.99 *	.99 *	.58				.79 *				-.33			
Pad 2		–	.99 *	.99 *		.53				.79 *				-.29		
Pad 3			–	.99 *			.48				.70 *				-.39	
Pad 4				–				.74 *				.79 *				-.04
HR QL1					–	.86 *	.91 *	.55	.50				.15			
HR QL2						–	.75 *	.62 *		.31				-.20		
HR QL3							–	.43			.47				-.02	
HR QL4								–				.50				-.26
Ep. 1									–	.90 *	.84 *	.87 *	.11			
Ep. 2										–	.90 *	.85 *		-.11		
Ep. 3											–	.90 *			.02	
Ep. 4												–				.34
V. 1													–	.83 *	.89 *	.57
V. 2														–	.83 *	.63 *
V. 3															–	.59
V. 4																–

Table 4.4
Results of the one-way repeated measures ANOVA

Dependent Variable	F (df)	Significance
HRQL	13.5 (3,30)	.000
Pad Weight (log 10)	103.4 (3,30)	.000
Episodes of UI	10.5 (3,30)	.000
Void Frequency	11.7 (3,30)	.000

Table 4.5
Significance between the time periods for each dependent variable using repeated contrasts

Measure	Time periods	F	P value
HRQL	1-2	0.07	.795
	2-3	1.93	.195
	3-4	22.21	.001 **
Pad Weight (transformed)	1-2	.48	.503
	2-3	6.07	.034
	3-4	166.8	.000**
Episodes	1-2	0	1.0
	2-3	0.09	.776
	3-4	20.3	.001**
Voiding Frequency	1-2	0.003	.961
	2-3	7.8	.019
	3-4	19.13	.001**

Degrees of freedom for all F scores (1,10)
Time period refers to the comparisons between time periods
** indicates P<.01

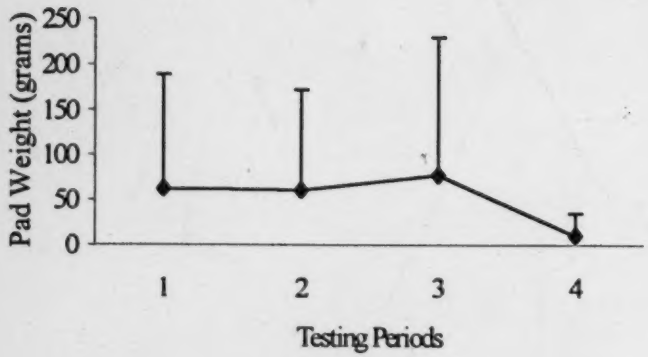

Figure 4.1 Mean change in pad weight (grams) over time (+SD).

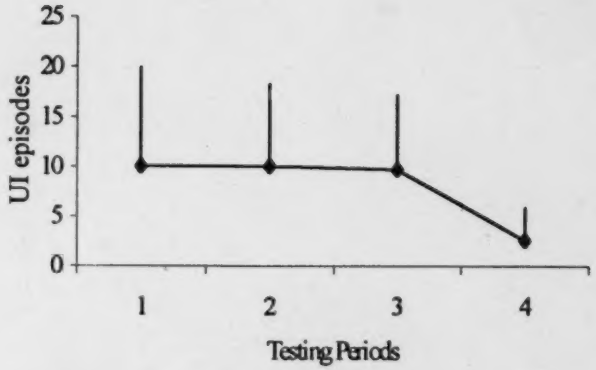

Figure 4.2 Mean change in the no. of UI episodes over time (+SD)

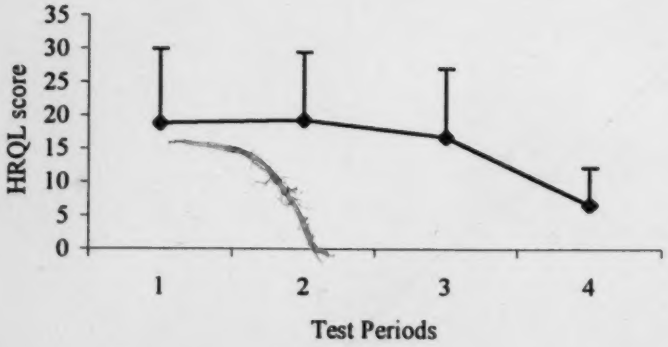

Figure 4.3 Mean change in HRQL score over time (+SD).

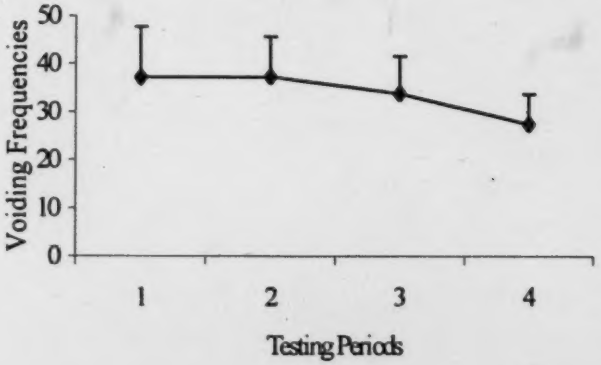

Figure 4.4. Mean change in voiding frequency over time (+SD).

Table 4.5

Significance between the time periods for each dependent variable using repeated contrasts

Measure	Time periods	F	P value
HRQL	1-2	0.07	.795
	2-3	1.93	.195
	3-4	22.21	.001 **
Pad Weight	1-2	.48	.503
(transformed)	2-3	6.07	.034
	3-4	166.8	.000**
Episodes	1-2	0	1.0
	2-3	0.09	.776
	3-4	20.3	.001**
Voiding Frequency	1-2	0.003	.961
	2-3	7.8	.019
	3-4	19.13	.001**

Degrees of freedom for all F scores (1,10)

Time period refers to the comparisons between time periods

** indicates P<.0

Chapter 5
Discussion and Conclusion

This study demonstrated that a physiotherapy intervention was effective in reducing the severity and quality of life of women suffering from stress and mixed UI. The results confirm the findings of other researchers who evaluated a combined (PFE, NMES plus education) therapy treatment approach (Davila & Bernier, 1995 and Fonda et al, 1995).

To our knowledge, this is the only study of conservative treatment of UI that used a repeated measures method to establish that the severity of UI was stable prior to treatment and improved after the intervention was applied. All dependent variables showed no significant difference across 3 pre-intervention testing periods spaced 6 weeks apart. The only significant difference in outcome measures occurred between the third pre-test and the post-treatment testing period.

Outcome Measures

The choice of outcome measures was based on the recommendations of the ACHRP Clinical Practice Guidelines (U.S. Dept. of Health and Human Services, 1996) and the validity and reliability reports provided by previous studies (Uebersax and Shumaker, 1994 and 1995; Versi, 1996; Wyman, 1988). There were a few irregularities in our data that must be questioned. Although pad weight and episodes of UI were highly related (Pearson's r between 0.68 and 0.82), there were two situations when the subjects reported no UI episodes but the pad test registered actual urine loss. Versi et al (1996) and Siltberg et al (1997) suggest that 4.0 grams per day of pad weight gain could occur through vaginal discharge or perspiration. In these cases, the weight in grams exceeded 4 grams (11.0, 21.0). We can only assume that the either the subjects were not aware of the urine loss episode, or missed recording it in their bladder diary.

The relationship between the impairment measures and HRQL are comparable to those in the original report on the UI-HRQL instrument. Shumaker et al (1994) published correlations of r=0.51 for relationship between HRQL and episodes of UI, and r=0.23 for the relationship between HRQL and pad weight. Our study resulted in a similar relationship (r = 0.31 - 0.50) for HRQL to episodes, and a stronger relationship (r = 0.48 -0.74) for HRQL to pad weight. The health-related quality of life instrument attempts to measure the social-emotional and practical impact of the UI condition. Several authors have proposed why HRQL measures are important to measure and why they do not necessarily relate perfectly to impairment measures (Benjamin, 1995; Lohr, 1998; Cole et al, 1994). Cole et al (1994) suggest that the

> "relationship between impairments, disabilities and handicaps is not linear – the magnitude of the handicap results not only from the interaction of the impairment and disability, but also from the individual's physical environment, social and economic setting and the resources available" p.163.

For instance, in our sample one subject's pre-intervention pad weights were 435g., 387g. and 528g., which were approximately 25 times greater than the mean of the other 10 subjects. Yet her HRQL scores were not the highest in the sample.

One of the 4 dependent variables, voiding frequency, was chosen for this study because, conceptually, it is a measure of severity for urge UI (ACHPR, U.S. Dept. of Health and Human Services, 1992), and we had intended to recruit subjects with urge UI, as well as with stress and mixed. This outcome measure reflects how often women suffering from incontinence must seek out toilet facilities over a specified time period (in our case, a 4-day period). Because no women with urge UI were in the study, we did not expect void frequency to change as much as the other dependent variables. It was interesting to note that there was a significant reduction in voiding frequency between pre-test and post-treatment measures, even though there were no urge subjects involved in the study (Table 4.1). Of the five mixed subjects, who by definition had urgency symptoms, 3 subjects had a lower post-test void score than any pretest voiding score. Of the six stress UI subjects, 5 had a lower post-test void score than any pre-test score. To our knowledge, no other study has reported a reduction in voiding frequency for stress UI and only one study (Holtedahl, 1998) reported a reduction in void frequency for an unspecified sample of subjects with UI. Physiotherapy treatment may have resulted in the reduction of voiding frequency in our sample, (even though it is not often reported as an outcome of treatment for non-urge UI) because subjects may be more confident of their ability to control urine loss and do not feel they need to preventively empty their bladders as frequently.

Voiding frequency, as a dependent variable, did not display the stability during the 3 pre-treatment tests that the other 3 measures did. Void frequency measures for 2 of the 11 subjects reduced each time they were tested. Recording voids and episodes of incontinence in a bladder diary can cause improvement in some subjects prior to initiation of treatment, as patients gain insight into their problem. Patients may pick up patterns of urgency, and automatically adjust behavior by increasing the time between voids.

Generalizability of Results

It is difficult to determine whether this sample of women with UI are representative of a larger population of UI sufferers, as it has been estimated that only 37% of incontinent women have ever told their doctor about, or sought treatment for UI (Burgio et al, 1994). Our sample, with a mean age of 56.3 was slightly younger than other studies, i.e. Shumaker et al (1994) whose sample was a mean of 61years and Berghman et al, (1996) with mean age of 59. However, the older subjects in our sample seemed to improve equally as well as their younger counterparts. The treatment-seeking population at this clinic has a mean age of 50.7 years, and a mean UI history of 8.9 years, making the study sample older by 5.6 years. Fifty-two percent of women receiving treatment at the clinic have a prolapse, whereas 45% (5 of 11 subjects) had a prolapse. This seems to indicate that the study sample is fairly typical, in age and gynecological history of the women who seek treatment at the Continence Clinic where this research was conducted.

The effect sizes calculated in this study are comparable with other published studies, indicating that the treatment, provided in this study, produced similar clinical improvements. Shumaker et al (1994) reported an effect size of 1.18 for the UI-HRQL instrument, whereas our sample improved from means of 10.5 to 5.5 for an effect size of 1.14. Effect size for pad tests vary in the literature from 1.1 (Bø et al, 1990) to 3.0 (Sand et al, 1995). The pad weight improvement in our study provided an effect size of 0.96 (with outlier removed). Burgio et al (1986) reported an effect size of 1.1 for episodes of UI, whereas this study produced an effect size of .89.

The significant improvements demonstrated by this study cannot be generalized to patients with urge UI. The initial research proposal stated that subjects with all 3 types of UI would be recruited. Unfortunately no subjects with urge UI were referred to the Continence Clinic during the allocated time period. There is little research evidence available on subjects with urge UI. Smith (1996) compared the effects of conservative treatment (specifically NMES) specifically on urge UI. This study compared NMES and anti-cholinergic medication as treatments for urge UI. They reported 50-72% improvement in the groups, but no significant difference between groups was detected.

The rationale for treating urge UI with PFM retraining is different than the rationale for stress UI. NMES and voluntary pelvic floor contractions are thought to be effective in inhibiting over-activity of the detrusor muscle through utilization of the negative feedback loop (Fall et al, 1986). Whereas, PFM retraining for stress UI is based on increasing the muscle tonus and power

of the perineal and periurethral muscles, to improve the urethra's occlusive action (Bourcier, 1990). In our study, the subjects with mixed UI seemed to respond to treatment as well as the stress UI subjects, although no statistical comparisons can be made due small sample sizes.

The treatment interventions in this study were provided by three very experienced physiotherapists who have specialized exclusively in women's incontinence treatment. We have acknowledged that the treatment program is dependent on therapists' clinical judgement and assessment skills. Therefore it may be difficult to generalize these results to other clinical settings where treatment is provided by physiotherapists who are not specialized in continence treatment, or by other health care workers with lesser knowledge and skills. On the other hand, the results suggest that these therapists are as effective in their treatments as the literature indicates for other centres.

Compliance to Treatment

Patients' compliance to treatment was estimated by both treating therapists and the patients. Estimates (7.8/10 from subjects and 7.9/10 for therapists) were high enough to suggest that all aspects of the program (attendance at appointments, doing the daily home exercises, amending diet and caffeine intake, etc.) were, at least partially, adhered to. We believe compliance is an important aspect of the intervention, since pelvic floor musculature, like any other muscle group, requires a consistent, repetitive and progressive program, if strength and endurance gains are to be realized. High compliance levels in this study could be attributable to the importance that subjects place on UI as a problem, or to the success that the 3 therapists had in motivating the subjects to comply. No studies we have found report on adherence / compliance other than to report drop outs or withdrawals from the study. Drop outs are often caused by concurrent medical problems, social crises, etc. and do not reflect actual participation in the treatment program.

Limitations of the Study

The intention of this study was to reflect current practice. Physiotherapists have been influenced by the current UI literature (Smith, 1996; Berghmann et al, 1998; Holtedahl et al, 1998; Bø K, 1998; Bo et al, 1999). The literature emphasizes that active pelvic floor exercises are crucial to the intervention, and that biofeedback and/or NMES can be useful if a voluntary pelvic floor muscle recruitment is not readily apparent. Since Bø et al (1988) demonstrated that 31% of incontinent women could not contract their pelvic floor muscles correctly, even after some

instruction, the modalities such as biofeedback and NMES are indicated for many patients. Therapists' clinical judgement is used to design an optimum muscle retraining program. The limitation of this study, as in the clinic setting, is that the relative contribution of the various modalities to the improvement cannot be determined.

This study used a repeated measures design rather than a control group design and may be influenced by certain biases. Subjects are sometimes influenced by the halo-effect when participating in a study. Their self-reports could have been influenced by a desire to please the treating therapists. The testing procedures, in this study, were described at each testing session,by the research coordinator, in efforts to maintain consistent data collection procedures.

It could be argued that subjects' improvement could be explained by regression towards the mean, as standard deviations reduced post-treatment. However, the repeated testing prior to treatment demonstrated that baseline measures were not significantly different. Clinically, UI sufferers demonstrate "good weeks and bad weeks", therefore testing pre-treatment status 3 times over 6 weeks provides strong evidence that the treatment caused the improvement.

Our study did not measure long term outcomes to treatment. We cannot determine if subjects were able to maintain their level of improvement after the treatment period ended. Only a few published studies report any follow up measurement. Fonda et al (1995) and Holtedahl et al (1998) reported that improvement in treatment groups was maintained, with only an 8-11% relapse after 6-12 month follow up periods. Dougherty et al (1993) reported a 10% relapse after a 2 year follow up. Burns et al (1993) reported that subjects not only maintained symptom improvement after treatment but that there was an actual increase in the cure-rate and a reduction in severity over a 6-month follow up period. In our study, patients were informed that PFE is a lifelong necessity, if continence is to be maintained. They were given a long term home program when the treatment period ended and were encouraged to contact the clinic if they were having problems with relapse.

Future Research

Future research into conservative treatment of UI should focus on 3 main areas discussed below.

1. Patient Characteristics

Clinicians need to know what patient characteristics predict good treatment outcomes. Because of the significant investment required by the client, in terms of compliance to treatment, and by the health care system, in terms of resources, it would be beneficial if clinicians could predict which

clients were mostly likely to benefit from treatment. Studies that stratify subjects (by pre-existing condition, age, medical history) are needed so that we can begin to understand the interaction between these characteristics and treatment.

2. Type of UI

There is little controlled research evidence to show that urge UI symptoms are improved with pelvic floor retraining, with or without NMES. Our study demonstrated that subjects with stress and mixed symptoms benefit, but only one study has specifically demonstrated positive effects for urge UI (Smith, 1996). Unfortunately, recruitment of urge subjects is difficult, due to lack of awareness by doctors that urge UI may respond physiotherapy.

3. Treatment in more general clinical settings

The treatment protocol provided in our study should be evaluated in other less specialized clinical settings so that we can determine if the positive results found in our study are generalizable beyond a specialized clinic in an urban tertiary hospital setting.

Conclusion

This study examined the effects of a physiotherapy program for females with urinary incontinence. Eleven women between ages 39 and 74 years participated in 3 pre-treatment testing periods, a treatment program (between 4 and 25 weeks duration), and a final post-treatment testing period. Six women had stress UI, and five had mixed UI. The treatment program consisted of a comprehensive history and physical assessment, education, an individualized pelvic floor muscle retraining program and home exercise program. Women and their therapists reported moderately high compliance to treatment (78-79%).

Four outcome measures were used. Involuntary urine loss was measured with a 48-hour pad test. Episodes of involuntary incontinence and voiding frequency were measured with a 4-day self-report bladder diary. A health-related quality of life measure designed specifically for female urinary incontinence was used to capture the change subjects' ability to cope and fulfill role functions. Each measure was tested four times (6, 3 and 0 weeks pre-treatment and immediately post-treatment).

Results showed a significant reduction in UI severity and impact of UI on quality of life, between the last pre-treatment test period and the post-treatment test period, whereas there were no changes in UI or HRQL during the three testing periods prior to treatment. In answering the initial research question, the results demonstrate that the physiotherapy program was effective in reducing the severity and the impact of female stress and mixed incontinence.

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Appendix A

UI – Health-related Quality of Life Questionnaire

This questionnaire asks you questions about how your incontinence affects your life and how it makes you feel.
Please answer every question. Make a mark in the box that corresponds to the number that most closely fits how you feel.

0 means - Not at all 1 means - slightly 2 means - moderately 3 means – greatly

	Has urine leakage affected your:	0	1	2	3
1	Ability to do household chores?				
2	Physical recreation such as walking, swimming etc.				
3	Entertainment activities such as movies, concerts, etc.				
4	Ability to travel by car or bus more than 30 minutes from home?				
5	Participation in social activities outside your home?				
6	Emotional health (nervousness, depression, etc.)				
7	Feeling frustrated?				
	Do you experience and, if so how much are you bothered by:	0	1	2	3
8	Frequent urination?				
9	Urine leakage related to the feeling of urgency?				
10	Urine leakage related to physical activity, coughing, etc.				
11	Small amounts of urine leakage?				
12	Difficulty emptying your bladder?				
13	Pain or discomfort in the lower abdomen or genital area?				
	Sub-Totals				
	TOTAL				

Subject Number _____

Appendix B

Women's Health Program
Royal Alexandra Hospital
Edmonton, Alberta

Evaluation of the Effectiveness of Physiotherapy for Female Urinary Incontinence

Principal Investigator: Chris Mummery, B.P.T.
Co-investigators: Cathy Flood, M.D.
Dianna MacDonald, Dip.P.T.

Background

This research project will help us to determine whether physiotherapy works to improve the severity of incontinence and quality of life.
Physiotherapy for urinary incontinence involves:

- A pelvic floor muscle assessment by the physiotherapist (this includes an internal examination)
- Pelvic floor muscle re-education which could include electrical stimulation, biofeedback and exercises for the pelvic floor muscles.
- A home program which consists of exercises and may include bladder training and diet modification.
- Women usually attend physiotherapy appointments 2 times per week for 10-20 weeks, depending on how quickly they progress. Each appointment last about 45-60 minutes.

In order for women to get the maximum benefit from therapy, it is essential that they attend all appointments consistently.

Purpose of the Research Project

This project compares the severity of each women's incontinence while she is waiting for treatment, with the severity of incontinence after completion of the therapy program. All subjects in the study will receive treatment, whether they choose to be in the study, or not.

Procedures

Testing

Firstly, you will be asked to attend an appointment at the beginning of the study to talk to a staff physiotherapist and receive all the information, so you can decide whether you wish to participate in the study. If you decide to be in the study, you will be asked to sign an Informed Consent Form. Testing will occur 4 times. Three times prior to treatment starting and once after you have completed your physiotherapy program.
Testing includes 3 things:

1. You will be asked to complete a 13-item questionnaire
2. You will be asked to keep track of the times when you have a urine leakage (accident) and the number of times you void for 4 days in a row (using a bladder diary form that is provided),
3. You will be asked to wear specially pre-weighed pads to catch any urine leakage for 48 hours (the last 2 days of your bladder diary). You must put the wet pads in the zip-lock bags provided and return them to the clinic for weighing.

You and the physiotherapist will agree on what day you will start the 4-day bladder diary. The used pads and the diary will either be dropped off by you at the hospital, or we can arrange for a research assistant to pick it up.

Withdrawing from the Study

You may, at any time, choose to drop out of the study without losing your place in the waiting list for physiotherapy. You are free to withdraw from the physiotherapy treatment progam at any time.

Possible Benefits

In participating in the project, you will receive therapy treatment, and will assist the medical and physiotherapy fields in knowing how to better help people with similar problems.

Possible Risks

There are no known side effects or risks from participating in physiotherapy treatment for incontinence. One aspect of physiotherapy treatment that may be recommended to you is neuro-muscular electrical stimulation. You should not have this treatment if you are pregnant, or if you have a pacemaker.

Confidentiality

All personal information obtained in the study will be seen only by the researchers and your physiotherapist. The study papers will use only a numeral identifier, instead of your name. Any study results that are presented or published will use combined data of all participants. Data will be stored in a locked room in the hospital during the study and for 7 years afterwards.

If you have any concerns about any aspects of this study, you may contact the **Patient Concerns Office of the Capital Health Authority at 474-8892.** This office has no affiliation with the investigators.

All participants may contact the investigators to ask questions at the following numbers:

Dianna MacDonald	Senior Program Therapist 477-4761
Dr. Cathy Flood	Physician in the Women's Clinic 477-4761

Your Physiotherapist: _____
477-4761

I, _____, have read the information provided in this letter and agree to participate in the research project, knowing I may withdraw at anytime.

_____ _____

Signature of patient Date

Appendix C

Women's Health Clinic

UI Study

Compliance to the Treatment Program

Please make a mark along the line below to estimate how much you were able to follow the therapy program that you have just completed.

Please remember that the program required you to:

- Attend appointments
- Do a home exercise program
- Write in you bladder diary
- Change some habits (such as drinking coffee, etc.)

Did not follow at all	Followed everything perfectly

Subject Number _____ VAS Measurement _____cm.

Women's Health Clinic
UI Study

Estimation of Patient Compliance to Treatment

Please make a mark on the line below to estimate how well this patient complied with all the requirements of the therapy program.

Patient Name _____

The requirements include:

- Attendance at appointments
- Consistency with the home exercise program
- Completing the bladder diary
- Making changes to lifestyle as recommended

_____

No compliance at all	Perfect Compliance

_____ _____

Therapist Signature Date

Subject Number _____ VAS Measurement _____cm.

Tests for Normal Distribution of Data

Measure	Kolmogrov-Smirnov Z score (df)	P
Episode 1	0.35 (11)	.000*
Episode 2	0.15 (11)	.20
Episode 3	0.23 (11)	.12
Episode 4	0.22 (11)	.16
HRQL 1	0.22 (11)	.17
HRQL 2	0.15 (11)	.20
HRQL 3	0.17 (11)	.20
HRQL 4	0.17 (11)	.20
Void 1	0.35 (11)	.05
Void 2	0.24 (11)	.09
Void 3	0.15 (11)	.20
Void 4	0.13 (11)	.20
Pad 1	0.49 (11)	.00*
Pad 2	0.38 (11)	.00*
Pad 3	0.40 (11)	.00*
Pad 4	0.43 (11)	.00*
Pad 1 (log 10)	0.29 (11)	.01*
Pad 2 (log 10)	0.24 (11)	.07
Pad 3 (log 10)	0.26 (11)	.03*
Pad 4 (log 10)	0.27 (11)	.03*

* indicates > 0.05 (significant difference from normal distribution)

Data Transformation for Pad Weight Data

	Pad weight (grams)				Log 10 Transformed			
Subject	Test 1	Test 2	Test 3	Test 4	Test 1	Test 2	Test 3	Test 4
1	10.9	10.8	11.0	3.2	1.04	1.03	1.04	0.51
2	13.6	10.7	13.0	1.3	1.13	1.03	1.11	0.11
3	435.3	387.4	528.0	83.0	2.64	2.59	2.72	1.92
4	19.3	26.1	27.6	1.8	1.29	1.42	1.44	0.26
5	19.9	26.3	30.8	3.8	1.30	1.42	1.49	0.58
6	30.3	23.8	27.2	3.2	1.48	1.38	1.43	0.51
7	15.2	16.8	14.5	1.4	1.18	1.23	1.16	0.15
8	14.7	17.4	21.0	4.7	1.17	1.24	1.32	0.67
9	96.5	94.1	105.4	10.0	1.98	1.97	2.02	1.00
10	9.7	7.5	25.8	3.7	0.99	0.88	1.41	0.57
11	21.5	44.5	46.3	5.0	1.33	1.65	1.67	0.70